

LinkSymphoKnee Primary TKA Outcomes

Clinical Outcomes Report
December 31, 2024

Purpose

The objective of this report is to present mid-term results for the LinkSymphoKnee implant system to aid US medical centers during the value-analysis committee review process.

This report of clinical outcomes includes patients who underwent primary total knee arthroplasty (TKA) with the LinkSymphoKnee implant system at multiple institutions in the United States.

Method

The inclusion criteria for this analysis were patients enrolled in the PatientIQ Platform who underwent primary TKA with the LinkSymphoKnee at multiple institutions in the United States. Standard patient-reported outcomes questionnaires for KOOS JR, PROMIS (multiple domains), and Veterans Rand 12 were administered at baseline and standard time points postoperatively. Results were reported from presurgery to up to 1-year post-surgery. The number of patients included per time point is shown below.

Results

Table 1. Patient Demographics

Demographics	
Patients	517
Surgeries	570
Age	69.7 ± 8.8
Sex	
Male	199 (38.5%)
Female	318 (61.5%)
Ethnicity	
American Indian or Alaska Native	2 (0.5%)
Asian	2 (0.5%)
Black or African American	30 (7.9%)
Other Race	26 (6.8%)
White	243 (63.6%)
Unknown	78 (20.4%)

In this multicenter cohort there were 517 patients (570 surgeries) that underwent a primary TKA with the LinkSymphoKnee implant at two institutions in the US. There were 318 females (61.5%) with an average age of 69.7 ± 8.8 years (Table 1).

Patient-reported outcome measures were collected preoperatively, 6-weeks postop (6WPO), 3-months postop (3MPO), 6-months postop (6MPO), and 1-year postop (1YPO) with results summarized below (Table 2).

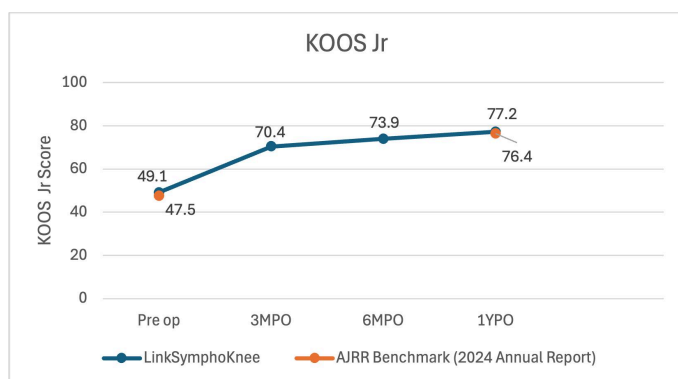
There are currently 2 year results available for 48 patients with an average KOOS Jr. score of 80.660 with a standard deviation of 16.808.

Table 2. Patient-Reported Outcomes

PROM Assessment	Preop (N)	6WPO	3MPO	6MPO	1YPO
KOOS JR	49.112 ± 14.092 (431)	63.382 ± 11.550 (220)	70.401 ± 12.915 (294)	73.935 ± 15.279 (260)	77.185 ± 15.288(184)
PROMIS Pain Interference	62.342 ± 6.409 (185)	NA	53.912 ±6.800 (111)	52.104± 8.888 (74)	50.368 ±9.507 (52)
PROMIS 10 - Physical Health	42.084 ± 6.826(186)	NA	48.281 ± 6.516 (104)	48.609 ± 7.370 (65)	49.878 ±8.557 (41)
PROMIS 10 - Mental Health	50.337± 8.266(186)	NA	52.384 ± 7.931 (104)	51.831 ± 8.649 (65)	52.976 ± 8.078 (41)
VR12 - Physical	35.048± 9.018 (221)	38.662 ± 9.347(208)	44.641± 11.715 (187)	45.817 ± 11.369 (190)	47.782 ±11.722 (150)
VR12 - Mental	54.339 ±11.222 (221)	49.719 ± 13.751 (208)	48.814 ± 16.285 (187)	47.439± 17.094 (190)	45.817 ± 17.321(150)

Note: PROMIS outcome scores were not available at the 6WPO.

Figure 1. KOOS JR Scores



In this multicenter cohort the average KOOS Jr at baseline was 49.112 ± 14.092 compared to 70.401 ± 12.915 , 73.935 ± 15.279 , and 77.185 ± 15.288 at 3 months, 6 months, and 1 year, respectively (Table 2). The national average for KOOS Jr is 76.4 ± 16.1 for all implants in the AAOS registry compared to 77.185 ± 15.288 for LinkSymphoKnee. Therefore, patients undergoing a primary TKA with LinkSymphoKnee have better KOOS Jr scores at 1 year post-surgery.

Moreover, a noteworthy 74% of patients within the LinkSymphoKnee cohort achieved the minimum clinically important difference (MCID) in KOOS Jr. scores at the one-year post-surgery assessment.

Figure 2. VR-12 - Physical Health Component Scores

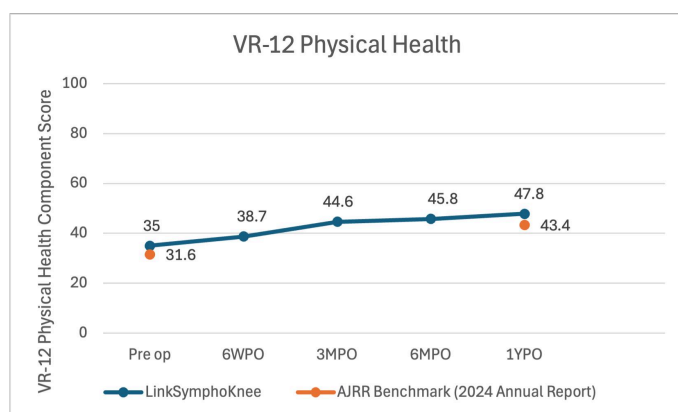


Figure 4. PROMIS 10 - Physical Health

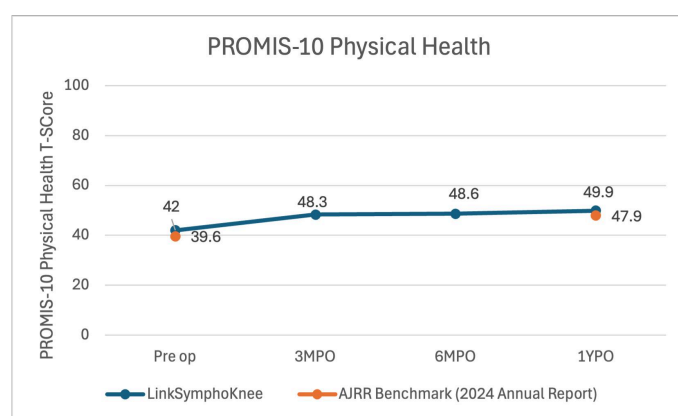


Figure 3. VR-12 - Mental Health Component Scores

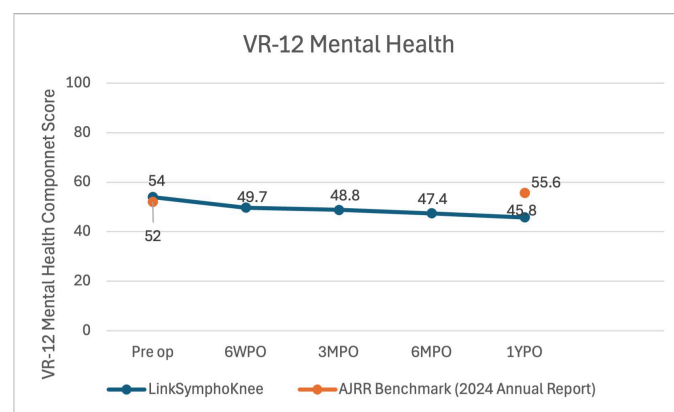
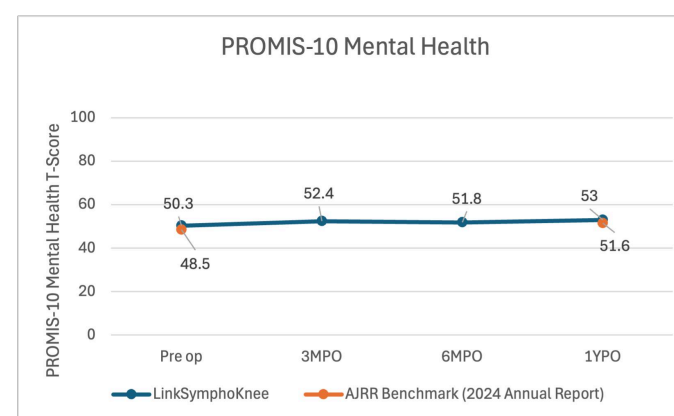


Figure 5. PROMIS 10 - Mental Health



Conclusion

In the present analysis, the LinkSymphoKnee cohort exhibited positive performance, surpassing all clinical function benchmarks established by the American Joint Replacement Registry (AJRR) in patient-reported outcomes at the one-year post-surgery. More than 74% of patients within the LinkSymphoKnee cohort achieved the minimum clinically important difference (MCID) in their KOOS Jr. scores at 1-year post-surgery.

While no claims can be made on the potential of these results without further analysis to determine statistical significance, the initial findings suggest a promising trend in favor of enhanced patient-reported outcomes for individuals who have undergone primary TKA with the LinkSymphoKnee system. Further investigations and analyses are warranted to substantiate these observations, and LINK plans to expand its LinkSymphoKnee registry data collection to provide a more comprehensive understanding of the long-term outcomes.